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FOOD BIO-SECURITY: FEDERAL/STATE/LOCAL COLLABORATION AND COOPERATION

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As we are all well aware, September 11, 2001, came crashing down on us like little else in the history of this nation. Despite our relative security at home through numerous wars, declared and undeclared, today we find ourselves faced with an enemy like no other. We are now forced, both in the U.S. and throughout the rest of the world, to make a tremendous paradigm shift in many areas of our daily lives. Though Europe and other parts of the world have dealt with aspects of terrorism for years, the first attack on the World Trade Center a few years ago was our first wake-up call to our own vulnerability to terrorism.

Although various parts of our government have been actively working on this issue for years, it is only recently that we have given much real attention to the possibility that our sources of food and water, both domestic and imports, may be a likely target for terrorists. September 11th has literally become the most important food safety issue we have faced in the last 30 years.

In this presentation I will attempt to discuss some of the actions we, meaning government, have taken to protect our food supply; contemplate the importance of real time communications among agencies; discuss the roles that our federal, state, and local health officials play in the area of food bio-security; and address what I consider to be issues that still need to be addressed. Due to the lack of time, I will address mainly the proactive (preventive) actions we must take to eliminate or reduce the likelihood of a bioterrorist event associated with our food supply, rather than discussing what actions we would take in the event of an actual bioterrorist event.

Federal Government: A Leadership Role

It is vitally important that our federal agencies take, and continue to play, a leadership role in the prevention of an attack on our food supply. The international implications of bioterrorism dictate that, to maintain uniformity in a regulatory system such as we have in the U.S., the States and local food safety programs must be able to depend upon our federal counterparts for advice, direction, and support. Yes, support. As anyone who deals with food-borne illness outbreaks and incidents of tampering will tell you, it is the States and the locals who are on the front lines and who are invariably the first responders in these types of situations. Consequently, we must have the support of our federal counterparts.

Our federal agencies must develop templates for re-engineering the inspectional process. Traditionally, we look at food safety with an eye on how foods may be accidentally contaminated. Today we must also examine how foods may be *intentionally* contaminated. This is a huge paradigm shift for the feds, the States, and for local regulatory officials. Therefore, not only must our federal regulatory agencies

develop these templates, but this information must be shared with the States. At the same time, federal agencies must also provide, or at least ensure, that State and local officials are provided the training necessary to make this shift. For years now federal, state, and local officials have been working very hard to develop and maintain a food safety system that eliminates as much duplication as possible, as well as a system that maintains as much uniformity as possible. Without federal leadership this would be impossible.

Federal agencies, working with private and State laboratories, academia, and regulated industry, must develop new methodologies to detect certain chemical and microbiological agents in any susceptible food. My understanding is that this is still a major drawback to developing new inspectional and sampling priorities.

Further, since more than 40 percent of the foods we consume in this country today are imported, federal agencies such as the FDA must have in place a system to ensure that foods entering the U.S. from foreign sources are just as safe as foods grown or produced here. Since the FDA currently has field inspectors capable of inspecting less than one percent of imports (although Congress recently authorized a huge increase in these numbers), FDA must fine tune and implement a system for not only the use of Equivalency Agreements with foreign governments, but must also have in place a system to monitor and verify that food safety systems in these countries are indeed equivalent and provide an equal protection against contamination, either inadvertent or as a bioterrorist action.

Our federal agencies must also have a good system in place for real time communications, both among themselves as well as with their State counterparts. This is one of the key elements of an adequate system to both prepare for, and react to, a bioterrorist threat or event.

In addition, Congress and our federal agencies must help build up the infrastructure for epidemiology, laboratory support, and surveillance within the States, in order to adequately prepare for, prevent, and respond to bioterrorist threat or event - especially any associated with food.

No less important is the interaction and communication between the federal agencies and the food industry. Since many of the recommendations for securing the food supply are not regulatory mandates, it will be industry that must implement the recommendations. At the same time, some bio-security issues are inter-related with current federal (and state) regulations. Consequently, federal (and state) officials must enter into discussions on the issues and practical solutions, including how future inspections will be conducted and the extent of recommendations the agencies can legally make, and *how* those recommendations will be made.

The Role of State and Local Food Safety Officials.

As I previously indicated, anyone who has dealt with food-borne illness outbreaks, complaints of almost any nature with respect to foods, and tampering events will tell you that the first responders are State and local food safety programs. In Texas we receive approximately 1,100 complaints from various sources each year, ranging from a hospital with patients showing symptoms of botulism intoxication, to a consumer complaining of unsanitary conditions in a restaurant. This doesn=t even include most complaints received by the 174 local health departments in Texas that regulate 80 percent of the 85,000

retail facilities. Consequently, State and local officials will most likely be the first to either discover or respond to a bioterrorist event.

Further, States today conduct 90 percent of the inspections of food processors throughout the U.S., excluding meat and poultry plants under USDA inspection. This amounts to more than 58,000 inspections per year. Since the FDA does not inspect nor have jurisdiction over retail facilities that do not engage in interstate commerce, virtually 100 percent of the almost one million retail facilities in the U.S. are inspected by State and local regulatory authorities. In addition, the FDA utilizes contracts with 36 states to conduct over 7,000 inspections of food processing facilities and food wholesalers in lieu of FDA inspections. USDA=s Food Safety and Inspection Service shares the costs of the inspection of the many State-inspected meat and poultry plants on a fifty-fifty basis. The result is a truly integrated National Food Safety System for ensuring that all facilities are adequately inspected based upon risk. Therefore, it is incumbent that federal agencies continue to supply the States with adequate financial support, training, and audits to ensure that our food supplies remain safe and that inspections provide an equivalent level of safety. This includes access to any revisions made as a result of the paradigm shift due to September 11th, currently in progress within the federal agencies, and the training necessary to ensure that we don=t end up with 50 different inspection models throughout the U.S.

Since most inspections of our domestic food manufacturers and wholesalers are conducted by the States, and since many potentially unsafe and uninspected foods still cross our borders, it is only logical that FDA should expand the State Food Inspection Contracts to include reviews of imported foods already in domestic commerce. Inspection of domestic imports used to be a part of these contracts but was dropped about 15 years ago. In fact, if you look closely at many of FDA=s food recall notices these days, you will observe that a very substantial portion of those recalls are initiated by one or more State agencies - not based upon FDA inspections but State inspections. Further, a majority of the recalls of imported foods are initiated by the States.

In fact, there is such a wealth of inspectional resources in the States, the USDA is currently considering a plan to pay the States to conduct the inspections of shell egg producers, while FDA plans to pay the States to conduct the environmental inspections, both under the joint USDA/FDA Salmonella enteritidis Reduction Plan.

My point is that there must be adequate communication, cooperation, and training between federal food safety agencies and their State and local counterparts. Without these essentials, and without partnerships between federal and state regulatory bodies, the system would simply collapse.

What Are the Current Realities?

As a representative and former President of the Association of Food and Drug Officials (AFDO), I participate in the activities of the Alliance for Food Security, a loose organization of industry associations and government officials under the leadership of one of our speakers today, Ms. Rhona Applebaum of the National Food Processors Association (NFPA). This interaction between some 70 industry associations and federal regulatory officials has been most effective so far, with both sides coming to an understanding of the principal issues affecting food bio-security. Since Rhona will address this activity in detail, I will not dwell on the activities of the Alliance here, except to say that we

are all embracing the concept of Operational Risk Management in the re-engineering of our inspectional activities and in general advice to industry.

Although our federal counterparts have provided certain general information to the states in such areas as pesticide application, foot and mouth disease, BSE, and general preparedness for a bioterrorist event, not too many specifics have yet emerged that will ensure uniformity in many of our activities. The FDA has published two documents in the *Federal Register* on the use of ORM for public comment. CDC is working closely with State epidemiology programs on coordination, communication, and expansion of FoodNet and PulseNet. The Environmental Protection Agency has outlined for State water programs the regulatory issues that are related to the bio-security of public drinking water sources. There have been many other activities as well, which represent good communications between State and federal agencies.

On the other hand, State legislatures, State Offices of Emergency Management, Boards of Health, and local city councils often act much swifter than our federal counterparts. New state laws can often be enacted much quicker than federal regulations or policy changes; and Boards of Health can enact new regulations at the State level almost overnight. Policy revisions by state agencies and programs can also be implemented rather swiftly. Often these entities, for political reasons or otherwise, are quick to require government agencies to make changes. Consequently, many states and localities have already implemented policy revisions and new inspectional procedures that may or may not be in conformance with those currently under consideration by our federal counterparts. This has the potential to become a new nightmare of non-uniformity for regulated industry.

State Activities.

There are a multitude of activities occurring at the State and local levels with respect to food bio-security. For example, California's Department of Health Services (DHS) has already developed new guidance documents on Operational Risk Management, and has incorporated ORM into their routine Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Point (HACCP) inspections. This is also being done by the Texas Department of Health, with other state food safety agencies throughout the country not too far behind. ORM training has also been included in routine training for investigators. California DHS has also implemented a "strike team" concept and an emergency notification system; while the Texas Department of Health has expanded their Disaster Response Team to include bioterrorism. These teams traditionally include such areas as epidemiology, laboratory, emergency management services, surveillance (sanitarians, food safety investigators), and communications activities. States are also developing pamphlets and flyers for their industries, identifying various ways they can improve the security of their products. State regulatory agencies are looking at various aspects of food bio-security and incorporating these issues into their inspectional procedures – issues directly associated with both GMP compliance as well as non-regulatory security issues.

As a simplified example, regulations already restrict certain areas of a food processing or retail facility to "authorized personnel only." Current regulations also require doors and windows that provide for direct access to food production and food storage areas be protected against entry by pests and dust. Since both issues are related to access to the food supply and equipment by unauthorized personnel, these biosecurity issues are directly tied to the current regulations.

On the other hand, issues related to the immigration status of employees, or limitations on access of employees from one area of a production facility to the other, are not covered by regulations but could be of keen importance to many companies in their efforts to improve security, and limit access to their foods, ingredients, and product packaging.

State food safety programs are also engaged in re-prioritizing establishment inventories with respect to the *risk* the foods or the activities pose. Traditionally both the States and federal food safety agencies have defined foods or activities as high, medium, or low risk based upon the history of the food as a vector of food-borne illness, the ability of such bacteria to rapidly reproduce in a given food, population exposure, as well as other factors. However, by incorporating biosecurity issues into the matrix, the States are finding that foods and/or facilities that traditionally were medium or low risk for food-borne illness are now at a high risk. Since these risk analyses are used as a risk management tool to prioritize establishment inspectional frequencies, food bio-security is having a significant impact on our State inspectional activities and priorities. This in turn is going to translate into a significant impact on certain segments of the food industry.
It is our hope at the State level that our federal counterparts are close behind in this effort, or once again we will have more non-uniformity between regulatory agencies.

Other ongoing activities at the State and local levels include development of new secure, real-time communications systems, new training for the staff involved in bio-security; development of a statewide pharmacy plan to ensure adequate supplies of pharmaceuticals needed in case of a bioterrorist event; significant expansion of our staff engaged in surveillance, epidemiology, and laboratory work; and development of an entirely new annex to the State Emergency Management Plan which includes contact names and phone numbers all the way down to city and county officials throughout the State.

Communications with regulated industry has been greatly enhanced, not only through flyers and increased activities during inspections, but also with information geared toward specific industries. For example, letters have been sent to the milk tanker operators and pesticide applicators concerning security of their tankers (seals) and lock-and-key control over pesticides.

State laboratories are also attempting to expand their capabilities and expertise, anticipating an expansion of samples to be analyzed.

What Still Needs To Be Done/What Does the Future Hold?

It is clear that in some ways State plans for reducing the likelihood of a bioterrorist event associated with our food supplies may be a step or two ahead of our federal counterparts, at least in implementation. The federal agencies therefore need to complete their new risk assessments for inspections, inspectional procedures, and for the risk posed by various categories of foods. Operational Procedures Manuals need to be revised. Then, the information must be *shared* with state counterparts to reduce or eliminated non-uniformity and at the same time add additional protection to our food supply.

Federal officials need to complete the paradigm shift by re-prioritizing establishment inventories based upon the new risk assessment. This will certainly impact the inventories of establishments that are assigned for inspection by the States under Food Inspection Contracts between FDA and the States.

Additional funding authorized by Congress should greatly assist the States and locals in building up their core capacities in epidemiology, laboratory, surveillance, and haz-mat to act and react to bioterrorism, again reminding us that the States and locals are almost always the first responders in similar situations.

Also, federal agencies must open up the communication lines with the States. Federal officials are justifiably concerned about "giving potential terrorists too much information." However, the type of information states are in need of is probably not so sensitive that it cannot be shared.

In addition, FDA should immediately modify State Food Inspection Contracts to include surveillance of imported foods already in domestic commerce. We know that FDA visually inspects less than one percent of imports. Since the States are already inspecting food wholesalers and transporters, it would seem both logical and a good idea to concentrate on food sources that have not been previously examined as most domestic sources have been.

FDA and USDA should increase the use of "equivalency agreements" with foreign governments to ensure that foods imported into the U.S. are at least as safe as domestically produced foods, but at the same time incorporate U. S. government oversight of these agreements to ensure they do indeed provide for equivalency. There have been several media stories lately that were highly critical of the lack of direct oversight of foreign inspection programs that, despite the use of these agreements, have allowed adulterated foods to enter the U.S.

FDA, USDA, and CDC need to continue to improve communication and collaboration. There is no more room for territorialism where the safety of our food supply is concerned. CDC should accept the laboratory support and expertise from not only state public health laboratories, but also the fine laboratories located in state departments of agriculture. Over 50 percent of the states locate food safety programs and labs in their agriculture departments rather than their departments of health.

The States also need to make some major improvements. We need to fully integrate our surveillance, epidemiological, and laboratory activities. We need to also put aside territorialism and increase our daily communications between offices and agencies.

The States also need to improve working relationships with the local health authorities. We need to provide more funding for core public health programs, as well as training and oversight. On the other side, the locals need to forget about "protecting their turf." If we did so, the increased surveillance of our food supply should translate into a much safer food supply overall.

For The Future:

We have often said that our food supply in the U.S. is the safest in the world. For many years we actually believed that not only was our food the safest, but that there was not a heck of a lot we could do to improve on our system of regulation. We had conquered botulism, not too many people were complaining about filthy foods, and apparently not too many people were reportedly becoming ill from eating contaminated food.

Then we began to improve our methods of detection of pathogenic bacteria and viruses; the public and physicians became more knowledgeable about food-borne illness, thus increasing the numbers of

illnesses reported to CDC; newly emerging and re-emerging pathogens began to appear; numbers of illnesses extrapolated from figures reported became more accurate; the percentage of imported foods significantly increased; and all of a sudden we realized we had a problem on our hands.

As a result, we have closer working relationships between federal agencies than ever before; we have developed performance-based regulations that are actually being enforced; we have improved recall and trace-back procedures and capabilities; we have FoodNet and PulseNet to more quickly identify food-borne illness outbreaks in order to limit their impact; federal agencies are working in closer cooperation with their State counterparts in what is becoming more of a National Integrated Food Safety System; Congress recently approved the hiring of an additional 600 or so FTEs for FDA, most of which will be used to increase surveillance of imported foods; and although much still remains to be done, generally we have responded admirably to many of the food safety issues we are facing today.

Can we translate this type of progress into an ability to protect our food supply from a bioterrorist's actions? One would hope so. I do believe Congress, the federal agencies, the States, our local governments, and regulated industry are all actively working to both reduce the likelihood that our food supply will be used for bioterrorism, as well as deal head-on with and reduce the impact of an actual event, if one should occur. None of us can predict whether or not an event will occur. Like so many things where science and medicine are involved, we can only work from what we know. We are aware of certain agents that could be used for an attack. We plan to protect against those agents. We develop new methodologies for detecting the presence of known chemical and microbiological contaminants. Our industries keep a closer vigil on their raw materials, water sources, finished products, and packaging. Food transporters do the same. Only time will tell if we have done enough.

The fact remains that we're in a new paradigm. We may never go back to the way things were in the past. And despite consumer advocate attitudes about government working closely with industry, bioterrorism is not just a regulatory issue, but an issue that has the potential to affect all of us.